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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,139	04/08/2004	Christopher W. Widenhouse	T2315-907821	6660

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MILES & STOCKBRIDGE PC
1751 PINNACLE DRIVE
SUITE 500
MCLEAN, VA 22102-3833

EXAMINER

CAMERON, ERMA C

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,139	WIDENHOUSE ET AL.	
	Examiner	Art Unit	
	Erma Cameron	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 15-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

1. Claims 15-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 10/17/2005.

The examiner acknowledges the election of the species, as well.

Claim Objections

2. Claim 1, 3 and 4 are objected to because of the following informalities:

a) claim 1 – spelling of Ph in line 3

b) claim 3 – there should be a comma after “vinylsulfonic acid”

c) Claim 4 – spelling of “pulysulfide”

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) There is no antecedent basis for

claim 1, line 3	said agent
claim 1, line 5	said surface
claim 2, line 2	said polymerizable agent
claim 2, line 3	the uncoated surface
claim 3, line 1	said substance
claim 8, line 1	said substance

b) Claim 2 does not agree with claim 1. Claim 1 states that the coating is on the surface. Claim 2 states that the polymerization is with the surface.

c) Claims 3 and 4 and 10: should be put into proper Markush terminology – selected from the group consisting of.

d) Claim 6: the use of the plural for the last two instances of “hydroxide” appears to be improper.

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e) Claims 10 and 11: claim 1 states that the radiation is gamma. Electron beam is improperly claimed in claims 10 and 11.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-12 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using an aqueous solution having a pH above about 8.0, does not reasonably provide enablement for any pH as in claim 1 (i.e. above or below 7.0). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It appears critical that the pH of the solution is above 8.0. See page 6.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g.,

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In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-4, 8 and 10-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 5100689. Although the conflicting claims are not identical, they are not patentably distinct from each other because '689 claims the substrate is adapted for contact with living tissue, whereas the instant application is silent on this. The instant application claims a pH, but the pH is unlimited, being defined as being above or below 7.0.

9. Claims 1-4 and 8-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 16 of U.S. Patent No. 5108776. Although the conflicting claims are not identical, they are not patentably distinct from each other because '689 claims the substrate is adapted for contact with living tissue, whereas the instant application is silent on this. The instant application claims a pH, but the pH is unlimited, being defined as being above or below 7.0.

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10. Claims 1-4, 8 and 10-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 5290548. Although the conflicting claims are not identical, they are not patentably distinct from each other because '689 claims the substrate is adapted for contact with living tissue, whereas the instant application is silent on this. The instant application claims a pH, but the pH is unlimited, being defined as being above or below 7.0.

11. Claims 1-4, 8 and 10-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 5885566. Although the conflicting claims are not identical, they are not patentably distinct from each other because '566 claims the substrate is adapted for contact with living tissue, whereas the instant application is silent on this. The instant application claims a pH, but the pH is unlimited, being defined as being above or below 7.0.

12. Claims 1-4, 8 and 10-11 are directed to an invention not patentably distinct from claim 12 of commonly assigned 5100689. Specifically, they are not patentably distinct from each other because '689 claims the substrate is adapted for contact with living tissue, whereas the instant application is silent on this. The instant application claims a pH, but the pH is unlimited, being defined as being above or below 7.0.

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13. Claims 1-4 and 8-11 are directed to an invention not patentably distinct from claims 1 and 16 of commonly assigned 5108776. Specifically, they are not patentably distinct from each other because '689 claims the substrate is adapted for contact with living tissue, whereas the instant application is silent on this. The instant application claims a pH, but the pH is unlimited, being defined as being above or below 7.0.

14. Claims 1-4, 8 and 10-11 are directed to an invention not patentably distinct from claim 11 of commonly assigned 5290548. Specifically, they are not patentably distinct from each other because '689 claims the substrate is adapted for contact with living tissue, whereas the instant application is silent on this. The instant application claims a pH, but the pH is unlimited, being defined as being above or below 7.0.

15. Claims 1-4, 8 and 10-11 are directed to an invention not patentably distinct from claim 14 of commonly assigned 588566. Specifically, other because '566 claims the substrate is adapted for contact with living tissue, whereas the instant application is silent on this. The instant application claims a pH, but the pH is unlimited, being defined as being above or below 7.0.

16. Claims 1-4, 8 and 10-11 are rejected under 35 U.S.C. 103(a) as being obvious over 5100689.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C.

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102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

17. Claims 1-4 and 8-11 are rejected under 35 U.S.C. 103(a) as being obvious over 5108776.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference

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under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

18. Claims 1-4, 8 and 10-11 are rejected under 35 U.S.C. 103(a) as being obvious over 5290548.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the

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reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C.

103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

19. Claims 1-4, 8 and 10-11 are rejected under 35 U.S.C. 103(a) as being obvious over 5885566.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claims 1-4, 8-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al (6387379).

'379 teaches treating a silicone or siloxane medical device (7:29-8:61) with monomers such as NVP at 0.1-50% conc. in solution and gamma radiation to polymerize a coating on the medical device. The dose and dose rate overlap with that claimed by applicant (8:63-9:67). The device may get a presoaking in a solution of 5-95% of the grafting monomer (11:1-36). Biofunctional agents such as drugs may be included in the coating (17:44-18:67).

'379 does not disclose the pH of the monomer solution, but applicant has claimed pH above and below 7.0, thus making pH unlimited.

'379 does not disclose that the device surface is hydrolyzed, but because the solution of the applicant and the solution of '379 are the same (same monomers, unlimited pH), it would be inherent that the hydrolysis would take place.

22. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al (6387379) taken in view of Darouiche et al (5902283).

'379 is applied here for the reasons given above.

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'379 does not teach regulating pH with a metal hydroxide.

'283 teaches that adding an alkanizing agent (to a pH of about 12) such as sodium hydroxide to a solution of an antimicrobial composition (such as antibiotics) that is to be applied to a silicone medical implant enhances the reactivity of the antimicrobial with the silicone of the medical implant (3:17-4:67; 6:14-18; Example 1).

It would have been obvious to one of ordinary skill in the art to have added the sodium hydroxide of '283 to the '379 process because of the teaching of '283 that the sodium hydroxide enhances the reactivity of a biofunctional agent such as an antibiotic to a silicone surface.

Conclusion


23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erma Cameron whose telephone number is 571-272-1416. The examiner can normally be reached on 8:30-6:00, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ERMA CAMERON
PRIMARY EXAMINER

November 12, 2005

Erma Cameron
Primary Examiner
Art Unit 1762